

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: December 30, 2019

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DEVON NICOLE INGBER,

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UNPUBLISHED

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Petitioner,

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No. 18-1061V

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v.

*

Special Master Nora Beth Dorsey

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SECRETARY OF HEALTH
AND HUMAN SERVICES,

*

Dismissal Decision; Human Papillomavirus

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("HPV") Vaccine; Meningococcal Vaccine;

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Transverse Myelitis ("TM"); Postural

Respondent.

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Orthostatic Tachycardia Syndrome

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("POTS").

* * * * *

Sol P. Ajalat, Ajalat & Ajalat, LLP, North Hollywood, CA, for petitioner.

Mallori B. Openchowski, U.S. Department of Justice, Washington, DC, for respondent.

DECISION¹

I. INTRODUCTION

On July 19, 2018, Devon Nicole Ingber ("petitioner") filed a petition under the National Vaccine Injury Compensation Program ("Vaccine Act" or "the Program"),² 42 U.S.C. § 300aa-10 *et seq.* (2012) alleging that as a result of receiving human papillomavirus ("HPV") vaccinations on November 10, 2010, June 15, 2011, and August 9, 2015, as well as a meningococcal vaccine on August 9, 2015, she suffered an autoimmune illness "differentially

¹ Because this Decision contains a reasoned explanation for the action in this case, the undersigned is required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the Decision will be available to anyone with access to the Internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, the undersigned agrees that the identified material fits within this definition, the undersigned will redact such material from public access.

² The National Vaccine Injury Compensation Program is set forth in Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C. §§ 300aa-10 to -34 (2012). All citations in this decision to individual sections of the Vaccine Act are to 42 U.S.C. § 300aa.

diagnosed as Postural Orthostatic Tachycardia Syndrome (“POTS”) and also Transverse Myelitis (“TM”).” Petition at Preamble. Respondent argued against compensation, stating that “this case is not appropriate for compensation under the terms of the Act.” Respondent’s Report (“Resp. Rept.”) at 1 (ECF No. 14).

After carefully analyzing and weighing the evidence presented in this case in accordance with the applicable legal standards, the undersigned finds petitioner failed to provide preponderant evidence that the vaccines she received caused POTS, TM, or an autoimmune condition. Therefore, this case must be dismissed.

II. PROCEDURAL HISTORY

The petition was filed on July 19, 2018, along with petitioner’s medical records and petitioner’s declaration. Petitioner’s Exhibits (“Pet. Exs.”) 1-3. Petitioner filed additional medical records on October 15, 2018. Pet. Ex. 4. On October 17, 2018, the parties filed a joint status report in which respondent’s counsel identified outstanding medical records. (ECF No. 8). The additional medical records were filed by petitioner on February 11, 2019, and a Statement of Completion was filed April 5, 2019. Pet. Exs. 5-6. On April 8, 2019, respondent filed his Rule 4(c) Report, recommending against compensation. Resp. Rept. at 1.

In his Report, respondent asserts that petitioner has not alleged a Table injury, and thus, she is not entitled to the presumption of causation afforded under the Table. Resp. Rept. at 10. Respondent further states that to prove causation, petitioner must provide evidence of medical theory connecting the vaccines to the injury, a logical sequence of cause and effect, and a temporal association between the vaccines and the injury. Id. at 10-11; see Althen v. Sec’y of Health & Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005). Respondent also contends that “[a]s a threshold matter, the medical records fail to provide preponderant proof that petitioner has been diagnosed with the conditions for which she seeks compensation, POTS and TM.” Resp. Rept. at 11.

On April 9, 2019, petitioner filed a response to respondent’s Report, stating that “[d]ue to the complexity and other factors related to petitioner’s disease process expert medical reports will be required.” Pet. Resp. to Resp. Rept., filed Apr. 9, 2019, at 2 (ECF No. 15). Petitioner further stated that she intended to seek expert reports in the “fields of autoimmune, neurological, vascular, pathological and biological diseases.” Id.

On April 17, 2019, a status conference was held by the special master assigned to the case at the time. After the status conference, petitioner was ordered to file her expert reports by July 31, 2019. In the interim, petitioner filed additional medical records on July 16, 2019. Pet. Ex. 7. Petitioner sought an extension of time to file her expert reports until September 30, 2019, which was granted. (ECF No. 20). Petitioner did not file an expert report. Instead, on September 23, 2019, she filed the current motion for judgment on the administrative record (“Motion”). Petitioner’s Motion (“Pet. Mot.”), filed Sept. 23, 2019 (ECF No. 21). In her Motion, petitioner states that she was unable to meet the requirements of the Vaccine Act. Id. at 1.

The case was reassigned to the undersigned on October 2, 2019. Respondent filed his response to petitioner's Motion ("Response") on October 7, 2019. See Resp. to Pet. Mot., filed Oct. 7, 2019 (ECF No. 23). In it, respondent requests that the petition be dismissed for the reasons set forth in his Report. Id. at 2. Petitioner filed a reply on October 12, 2019. See Reply to Resp. ("Reply"), filed Oct. 12, 2019 (ECF No. 24).

In her Reply, petitioner states that she is not requesting a dismissal of her petition on the basis of an alleged failure to meet the Althen requirements. Reply at Preamble. Instead, she states her motion is "based upon the inability of [p]etitioner to 'support an adequate recovery due to the disease and related processes from which [p]etitioner has been and is suffering.'" Id. at ¶ 1. However, in contrast to the prior statements, and in the same pleading, petitioner asserts that the records do support a viable claim. Id. at ¶ 3.

Specifically, petitioner states that on July 31, 2015, she had a sore throat and fever, and was diagnosed with viral pharyngitis. Reply at ¶ 3(a). Petitioner states that she was still ill with this condition when the vaccines at issue were administered to her on August 9, 2015, which caused "an over-activation of her immune system, developing into an autoimmune disease process." Id. She believes that onset of her autoimmune condition "commenced on August 12, 2015, with left nostril nose bleeds, along with a medical assessment of sinusitis and pharyngitis, the development of right lower abdominal pain, as well as mildly elevated ESR and CPR." Id. at ¶ 3(b). Petitioner alleges that her condition progressed so that by August 21, 2015, twelve days post-vaccination, she had a "headache, fatigue, malaise, left pleuritic chest pain, back pain," as well as many other symptoms and problems, including a non-specific finding on her MRI, all of which indicated "an autoimmune disease process." Id. at ¶ 3(c)-(d). Lastly, petitioner states that respondent's failure to address these issues in his Report is "indicative of the need for this Motion for Judgment . . . and the ability of [p]etitioner if so determined to elect a civil remedy." Id. at ¶ 6.

This matter is now ripe for adjudication.

III. FACTUAL SUMMARY

A. Factual Background Set Forth in Respondent's Report

After reviewing all of the medical records filed, the undersigned finds that respondent's Report provides an accurate summary of the petitioner's medical records, and thus, the undersigned adopts and incorporates it herein, as if fully set forth.

B. Medical Records Filed After Respondent's Report

Petitioner filed updated medical records after respondent filed his Report, and a brief summary of these records is indicated here. The summary provided by respondent ends at petitioner's office visit on June 7, 2018. See Resp. Rept. at 9-10. This summary picks up at the next relevant entry.

On December 10, 2018, petitioner presented to Dr. Ali Razfar, an ENT surgeon, for a pre-operative visit prior to a bilateral tonsillectomy. Pet. Ex. 7 at 4, 6. The records indicate that petitioner had recurrent tonsillitis since 2015. Id. at 5. Petitioner's physical examination was normal except that her tonsils were 1+. Id. The pre-operative records document that petitioner participated in four days of moderate to strenuous exercise every week. Id. at 10. Petitioner's tonsillectomy surgery was performed on December 20, 2018. Id. at 138. She tolerated the procedure well. Id.

On February 26, 2019, petitioner went to the emergency room with left lower quadrant abdominal pain. Pet. Ex. 7 at 141. She was referred to urology for a "likely congenital bladder cyst." Id. at 150. An ultrasound done on March 1, 2019 showed a cystic structure anterior to the bladder. Id. at 41. On April 17, 2019, the records state that petitioner had a "[n]on-communicating urachal cyst."³ Id. at 152.

The last entry is for a complaint of chronic neck pain on April 22, 2019. See Pet. Ex. 7 at 89. Based on that record, and a reference to a visit on November 15, 2018, it appears that petitioner was prescribed Tramadol for her neck pain. Id. at 96-98.

None of the updated records filed by petitioner state that petitioner was diagnosed with an autoimmune condition, TM, or POTS.

C. Petitioner's Declaration

In her declaration, the petitioner stated that prior to the vaccinations at issue, she had been healthy and physically active. Petitioner's Declaration ("Pet. Decl.") at ¶ 2. On July 31, 2015, she developed a sore throat and fever that progressed to a runny nose. Id. at ¶ 3. She still had these symptoms when she sought treatment from her health care provider on August 9, 2015. Id. at ¶ 4. At that visit, her doctor recommended the HPV and meningococcal vaccines. Id.

On August 12, 2015, she sought treatment because she continued to have a sore throat, and was "congested, coughing, vomiting and . . . and bleeding from [her] left nostril." Pet. Decl. at ¶ 5. Petitioner was diagnosed with sinusitis and pharyngitis. Id. She returned to her physician August 17, 2015, for continued symptoms along with lower right abdominal pain. Id. at ¶ 6. Her symptoms progressed and by August 21, 2015, she had a "sharp headache, dizziness upon standing, unsteadiness when walking," and neck pain. Id. at ¶ 7. Petitioner also had left sided weakness, chest pain, shortness of breath, and numbness in her fingers and toes. Id.

On October 15, 2016, petitioner states that she had severe right sided abdominal pain and underwent an appendectomy. Pet. Decl. at ¶ 8. As of the date that she signed the declaration, July 13, 2018, petitioner states that she continued to have migraine headaches, light sensitivity, nausea, dizziness, joint pain, toe cramps, fatigue, racing heart, eye distance weakness, severe

³ A urachal cyst is "a congenital anomaly in which part of the urachus is dilated to form a cyst." Dorland's Illustrated Medical Dictionary 461 (32d ed. 2012). A urachal cyst "may contain mucinous fluid, cellular debris, or urine." Id.

pain during her menstrual cycle, areas of whiteness in her hands and feet, reduced hearing, memory loss, nightmares, and other problems. Id. at ¶ 9.

IV. LEGAL AUTHORITY AND ANALYSIS

A. Standards for Adjudication

The Vaccine Act was established to compensate vaccine-related injuries and deaths. § 10(a). “Congress designed the Vaccine Program to supplement the state law civil tort system as a simple, fair and expeditious means for compensating vaccine-related injured persons. The Program was established to award ‘vaccine-injured persons quickly, easily, and with certainty and generosity.’” Rooks v. Sec’y of Health & Human Servs., 35 Fed. Cl. 1, 7 (1996) (quoting H.R. Rep. No. 908 at 3, reprinted in 1986 U.S.C.C.A.N. at 6287, 6344).

Petitioner’s burden of proof is by a preponderance of the evidence. § 13(a)(1). The preponderance standard requires a petitioner to demonstrate that it is more likely than not that the vaccine at issue caused the injury. Moberly v. Sec’y of Health & Human Servs., 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010). In particular, petitioner must prove that the vaccine was “not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury.” Id. at 1321 (quoting Shyface v. Sec’y of Health & Human Servs., 165 F.3d 1344, 1352-53 (Fed. Cir. 1999)); see also Pafford v. Sec’y of Health & Human Servs., 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner who satisfies this burden is entitled to compensation unless respondent can prove, by a preponderance of the evidence, that the vaccinee’s injury is “due to factors unrelated to the administration of the vaccine.” § 13(a)(1)(B).

B. Diagnosis

The Federal Circuit has made clear that “identifying [the petitioner’s] injury is a prerequisite” to the Althen analysis. Broekelschen v. Sec’y of Health & Human Servs., 618 F.3d 1339, 1346 (Fed. Cir. 2010). However, it is not necessary to diagnose an exact condition. The Federal Circuit has explained: “[T]he function of a special master is not to ‘diagnose’ vaccine-related injuries, but instead to determine ‘based on the record evidence as a whole and the totality of the case, whether it has been shown by a preponderance of the evidence that a vaccine caused the [petitioner’s] injury.’” Andreu v. Sec’y of Health & Human Servs., 569 F.3d 1367, 1382 (Fed. Cir. 2009) (quoting Knudsen v. Sec’y of Health & Human Servs., 35 F.3d 543, 549 (Fed. Cir. 1994)). “[T]he Special Master [is] not required to perform an Althen analysis . . . ‘in the absence of a showing of the very existence of any *specific injury* of which the petitioner complains.’” Lasnetski v. Sec’y of Health & Human Servs., 696 F. App’x 497, 506 (Fed. Cir. 2017) (quoting Lombardi v. Sec’y of Health & Human Servs., 656 F.3d 1343, 1352-53 (Fed. Cir. 2011)).

C. Causation

To receive compensation under the Program, petitioner must prove either: (1) that she suffered a “Table Injury”—i.e., an injury listed on the Vaccine Injury Table—corresponding to a vaccine that she received, or (2) that she suffered an injury that was caused by a vaccination. See

§§ 11(c)(1), 13(a)(1)(A); Capizzano v. Sec’y of Health & Human Servs., 440 F.3d 1317, 1319-20 (Fed. Cir. 2006). Petitioner must show that the vaccine was “not only a but-for cause of the injury but also a substantial factor in bringing about the injury.” Moberly, 592 F.3d at 1321 (quoting Shyface, 165 F.3d at 1352-53).

Because petitioner does not allege that she suffered a Table injury, she must prove that a vaccine caused her injury. To do so, she must establish, by preponderant evidence: (1) a medical theory causally connecting the vaccine and his injury (“Althen Prong One”); (2) a logical sequence of cause and effect showing that the vaccine was the reason for his injury (“Althen Prong Two”); and (3) a showing of a proximate temporal relationship between the vaccine and his injury (“Althen Prong Three”). § 13(a)(1); Althen, 418 F.3d at 1278.

The causation theory must relate to the injury alleged. Thus, petitioner must provide a reputable medical or scientific explanation that pertains specifically to this case, although the explanation need only be “legally probable, not medically or scientifically certain.” Knudsen, 35 F.3d at 548-49. Petitioner cannot establish entitlement to compensation based solely on assertions. Rather, a vaccine claim must be supported either by medical records or by the opinion of a medical doctor. § 13(a)(1). In determining whether petitioner is entitled to compensation, the special master shall consider all material contained in the record, including “any . . . conclusion, [or] medical judgment . . . which is contained in the record regarding . . . causation.” § 13(b)(1)(A).

D. Analysis

i. Diagnosis

As described above, in order to be entitled to compensation under the Vaccine Act, a petitioner must show a vaccine-related injury. In her petition, the petitioner alleges that she suffered an autoimmune illness of either POTS or TM. With regard to POTS, the undersigned has reviewed all of the petitioner’s medical records and found no reference to POTS. POTS did not appear even as a possible or differential diagnosis in petitioner’s records. Therefore, the undersigned finds that there is no evidence to support a vaccine-related injury based upon a diagnosis of POTS.

In the alternative, petitioner alleges that she suffered from TM. The medical records do state that TM was a differential diagnosis. On August 25, 2015, petitioner had a neurological evaluation by Dr. Nirmala Gowrinathan, and he noted a concern for post-infectious TM. Pet. Ex. 3 at 1637-40. Subsequently, petitioner underwent extensive neurology, rheumatology, and infectious disease workups, which were all negative. Id. at 1641-46.

In the hospital discharge summary dated August 27, 2015, Dr. Andrea Hawthorne stated, “[i]nitial differential diagnosis included post-infectious transverse myelitis. MRI cervical and thoracic spine was normal, ruling myelitis out.” Pet. Ex. 3 at 1555. Dr. Ashitosh Bhansali also wrote a discharge summary documenting the same conclusion: “Given history of weakness in the presence of fever and URI [upper respiratory infection] transverse myelitis was a working diagnosis. . . . An MRI cervical and thoracic spine was subsequently performed without signs of

myelitis.” Id. at 1560. These records show that TM was a differential diagnosis, diagnostic studies were done to determine whether petitioner had TM, and the studies revealed petitioner did not have TM. Therefore, the undersigned finds that petitioner failed to prove by preponderant evidence that she had TM.

Lastly, the petition and subsequent filings make references to petitioner having a vaccine-related autoimmune condition. Petitioner underwent an extensive rheumatology workup in August 2015 and saw rheumatologist Dr. Minh Chau Thi Nguyen for a follow up appointment on October 15, 2015. Pet. Ex. 3 at 162-67. Dr. Nguyen noted that petitioner was “feeling better” and “[n]o longer having fevers.” Id. at 164. Dr. Nguyen also stated that petitioner had “extensive rheumatologic testing which was all negative.” Id. at 167. Dr. Nguyen concluded that there was nothing “to suggest an active underlying systemic autoimmune disease or [i]nflammatory polyarthritis.” Id.

Of note, on November 10, 2015, petitioner had a neurology follow up appointment. Pet. Ex. 3 at 173. Neurologist Dr. Meriam Makary-Botros noted that petitioner was “[c]ontinuing to improve.” Id. at 176. Dr. Makary-Botros also noted that petitioner’s weakness was “[l]ikely postviral.” Id.

Approximately one year later, on October 31, 2016, petitioner had a follow up rheumatology appointment. Pet. Ex. 3 at 264. Petitioner was then eighteen years old, going to school, and working as a hostess. Id. at 264, 266. The rheumatologist reiterated that all prior testing had been negative, and there was nothing to suggest an autoimmune diagnosis. Id. at 269.

Based on her review of the petitioner’s medical records, and the statements in the records made by petitioner’s treating physicians, the undersigned finds that there is no evidence that petitioner sustained a vaccine-related autoimmune illness.

ii. Althen Prong One: Petitioner’s Medical Theory

Under Althen Prong One, petitioner must set forth a medical theory explaining how her vaccines could have caused her alleged injuries. Andreu, 569 F.3d at 1375; Pafford, 451 F.3d at 1355-56. Petitioner’s theory of causation must be informed by a “sound and reliable medical or scientific explanation.” Knudsen, 35 F.3d at 548; see also Veryzer v. Sec’y of Health & Human Servs., 98 Fed. Cl. 214, 223 (2011) (noting that special masters are bound by both § 13(b)(1) and Vaccine Rule 8(b)(1) to consider only evidence that is both “relevant” and “reliable”). If petitioner relies upon a medical opinion to support her theory, the basis for the opinion and the reliability of that basis must be considered in the determination of how much weight to afford the offered opinion. See Broekelschen, 618 F.3d at 1347 (“The special master’s decision often times is based on the credibility of the experts and the relative persuasiveness of their competing theories.”); Perreira v. Sec’y of Health & Human Servs., 33 F.3d 1375, 1377 n.6 (Fed. Cir. 1994) (stating that an “expert opinion is no better than the soundness of the reasons supporting it” (citing Fehrs v. United States, 620 F.2d 255, 265 (Ct. Cl. 1980))).

Here, petitioner did not offer any expert medical opinion or report in support of her claims. Further, petitioner’s medical records do not include any statement that could be

interpreted as a medical theory as to how the HPV and/or meningococcal vaccine can cause POTS, TM, or autoimmune illness. Petitioner's treating physicians did not offer any opinions as to a medical theory to explain how the vaccines could cause POTS, TM, or an autoimmune disease. Therefore, the undersigned finds petitioner failed to provide preponderant evidence to support Althen Prong One.

iii. Althen Prong Two: Logical Sequence of Cause and Effect

Under Althen Prong Two, petitioner must prove by a preponderance of the evidence that there is a "logical sequence of cause and effect showing that the vaccination was the reason for the injury." Capizzano, 440 F.3d at 1324 (quoting Althen, 418 F.3d at 1278). "Petitioner must show that the vaccine was the 'but for' cause of the harm . . . or in other words, that the vaccine was the 'reason for the injury.'" Pafford, 451 F.3d at 1356 (internal citations omitted).

Since there is no evidence of a theory of causation to support Althen Prong One, it follows that there is also no evidence to support a finding of a logical sequence of cause and effect to establish that the vaccines caused the petitioner's alleged injuries in this case. Although petitioner's physicians may have noted the fact that she received the vaccines and may have noted the petitioner's parents' concerns that her symptoms may have been related to her vaccines, there is no opinion expressed by her physicians as to vaccine causation. There is no evidence in the record to show that petitioner's treating physicians expressed an opinion that the vaccines caused petitioner's alleged injuries here. Further, after extensive diagnostic workups were completed, petitioner's physicians concluded that petitioner's symptoms were "possibl[y]" and "likely" post-viral. Pet. Ex. 3 at 167, 176. Therefore, the undersigned finds that petitioner failed to prove Althen Prong Two.

iv. Althen Prong Three: Proximate Temporal Relationship

Under Althen Prong Three, petitioner must provide "preponderant proof that the onset of symptoms occurred within a time frame for which, given the understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact." De Bazan v. Sec'y of Health & Human Servs., 539 F.3d 1347, 1352 (Fed. Cir. 2008). The acceptable temporal association will vary according to the medical theory advanced in the case. See Pafford, 451 F.3d at 1358. A temporal relationship between a vaccine and an injury, standing alone, does not constitute preponderant evidence of vaccine causation. See, e.g., Veryzer, 100 Fed. Cl. at 356 (explaining that "a temporal relationship alone will not demonstrate the requisite causal link and that petitioner must posit a medical theory causally connecting the vaccine and injury").

Petitioner has failed to provide any evidence showing the time frame between her vaccinations and the onset of her symptoms is medical appropriate to support vaccine causation. Further, there is no statement or opinion that the time frame between vaccination and her symptoms was medically appropriate to infer vaccine causation. Therefore, the undersigned finds that petitioner failed to provide proof of Althen Prong Three.

V. CONCLUSION

It is clear from the medical records that petitioner went through a period of illness and that her parents were concerned for her well-being, and the undersigned extends her sympathy to them for the hardships they experienced. However, the decision in this case cannot be based upon sympathy for the petitioner or her parents but rather an analysis of the evidence.

For the reasons discussed above, the undersigned finds that petitioner has not established by preponderant evidence that she is entitled to compensation and her petition must be dismissed. In the absence of a timely filed motion for review pursuant to Vaccine Rule 23, the Clerk of the Court **SHALL ENTER JUDGMENT** in accordance with this Decision.

IT IS SO ORDERED.

s/Nora Beth Dorsey
Nora Beth Dorsey
Special Master